Initial Approval: January 14, 2015

CRITERIA FOR PRIOR AUTHORIZATION

Direct Acting Hepatitis C Agent

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:

Viekira Pak™ (ombitasvir/paritaprevir/ritonavir and dasabuvir)

CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 24 weeks of Viekira Pak therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Must be used in combination with ribavirin unless patient has genotype 1b without cirrhosis
- Patient must not have been on a previous or concurrent direct acting hepatitis C agent (i.e. past or concurrent therapy with Incivek®, Victrelis®, Olysio®, Sovaldi®, or Harvoni®)
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Dose must not exceed 1 daily dose pack per day (2 ombitasvir/paritaprevir/ritonavir and 2 dasabuvir tablets per day)
- Patient must have one of the following:
 - Advanced fibrosis (Metavir F3)
 - Compensated cirrhosis
 - Liver transplant
 - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (eg, vasculitis)
 - o Proteinuria
 - Nephrotic syndrome
 - Membranoproliferative glomerulonephritis

RENEWAL CRITERIA:

- Prescriber must document adherence by patient of greater than or equal to 90% and meet one of the following:
 - o Genotype 1a with cirrhosis or mixed genotype with cirrhosis up to 24 weeks total therapy
 - Liver transplant recipient with normal hepatic function and mild fibrosis (Metavir fibrosis score 2 or lower) – 24 weeks total therapy
 - Genotype 1a without cirrhosis, mixed genotype without cirrhosis or genotype 1b with or without cirrhosis 12 weeks total therapy

LENGTH OF APPROVAL FOR VIEKIRA PAK: 4 weeks